

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

TRUTEK CORP.,

Plaintiff,

v.

Case No. 2:21-cv-10312

BLUEWILLOW BIOLOGICS, INC.;
ROBIN ROE 1 through 10, gender
neutral fictitious names; and ABC
CORPORATION 1 through 10 (fictitious
names).

Hon. F. Kay Behm

Defendants.

**DEFENDANT/COUNTER-PLAINTIFF BLUEWILLOW BIOLOGICS,
INC.'S REPLY IN SUPPORT OF BRIEF REGARDING MOOTNESS OF
THE CASE**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	ARGUMENT.....	1
A.	Relief in this Case Must Be Limited to NanoBio [®] Protect.....	2
B.	Trutek’s Request for Injunctive Relief Is Moot	4
C.	Trutek Lacks Standing to Maintain the Case, Which Must Be Dismissed	6
D.	The Court Should Decline to Consider Trutek’s Untimely and Speculative Request for Declaratory Relief.....	7
E.	There Are No Additional Unresolved Matters Which Would Justify This Case Continuing	8
III.	CONCLUSION.....	10

TABLE OF AUTHORITIES

	Page(s)
<u>Cases</u>	
<i>Abbott Diabetes Care, Inc. v. DexCom, Inc.</i> , No. 05-590 GMS, 2006 WL 2375035 (D. Del. Aug. 16, 2006)	3
<i>Already, LLC v. Nike, Inc.</i> , 568 U.S. 85 (2013)	3, 5
<i>Am. Meat Inst. v. Pridgeon</i> , 724 F.2d 45 (6th Cir. 1984)	9
<i>Amgen v. F. Hoffman-LaRoche Ltd.</i> , 456 F. Supp. 2d 267 (D. Mass. 2006)	3, 8
<i>Amgen, Inc. v. Hoechst Marion Roussel, Inc.</i> , 3 F. Supp. 2d 104 (D. Mass. 1998)	3
<i>Benitec Australia, Ltd. v. Nucleonics, Inc.</i> , 495 F.3d 1340 (Fed. Cir. 2007)	3
<i>Cardinal Chem. Co. v. Morton Int’l, Inc.</i> , 508 U.S. 83 (1993)	7
<i>Friends of the Earth, Inc. v. Laidlaw Env’t Servs. (TOC), Inc.</i> , 528 U.S. 167 (2000)	5
<i>GE Co. v. Nintendo Co., Ltd.</i> , 179 F.3d 1350 (Fed. Cir. 1999)	7
<i>Microsoft Corp. v. DataTern, Inc.</i> , 755 F.3d 899 (Fed Cir. 2014)	2
<i>Sierra Club v. U.S. Fish & Wildlife Serv.</i> , 189 F. Supp. 2d 684 (W.D. Mich. 2002)	7
<i>Sinclair & Carroll Co. v. Interchemical Corp.</i> , 325 U.S. 327 (1945)	7

<i>Smith ex rel. Smith v. Mount Pleasant Public Schools</i> , 298 F. Supp. 2d 636 (E.D. Mich. 2003).....	9
<i>Steel Co. v. Citizens for a Better Env't</i> , 523 U.S. 83 (1998).....	6
<i>Telectronics Pacing Sys. v. Ventritex, Inc.</i> , 982 F.2d 1520 (Fed. Cir. 1992)	3
<u>Statutes</u>	
35 U.S.C. § 271(e)(1).....	1, 3

I. INTRODUCTION

Trutek no longer has standing to maintain this action, its only claims for relief are moot, and it is not entitled to any additional, unpled declaratory relief. Trutek's arguments to the contrary are unavailing as they are premised on BlueWillow's developmental vaccines which are not a part of this case and, indeed, Trutek's attempts to include them were soundly rejected by the Court. As there is nothing left for the Court to do, this case should be dismissed with prejudice.

II. ARGUMENT

Trutek admits "it cannot currently proceed with claims based on the developmental vaccines." ECF 93 at 9. For that reason, its Response can be almost entirely discarded. Many of Trutek's arguments are premised on the unsupported assertion that the NanoBio[®] Protect formulation is the same as that used in BlueWillow's developmental vaccines and, thus, still within the purview of the court. However, Trutek is unable to cite to any evidence in this case that supports its idea as no discovery has occurred for the vaccines. Trutek's unsupported assertions are demonstrably false as well. Further, Trutek's attempt to include BlueWillow's developmental vaccines in this case has already been rejected as all activity related to those vaccines is protected by the safe harbor of 35 U.S.C. § 271(e)(1). ECF 32. Trutek's improper attempt to circumvent the Court's order should not be permitted.

Trutek only requested two forms of relief in this case: one has already been denied (damages)¹ and the other (injunction) can be dispensed of as easily. With no relief to be afforded, Trutek's claims are moot and the case must be dismissed for lack of standing. Trutek's belated attempt to seek declaratory relief does not convey the needed standing, nor does its pending Motion for Reconsideration (ECF 89).

A. Relief in this Case Must Be Limited to NanoBio[®] Protect

As firmly established, the only accused product in this case is NanoBio[®] Protect. It is the only product actually litigated and any similarities to other BlueWillow products has not been established. *See Microsoft Corp. v. DataTern, Inc.*, 755 F.3d 899, 911 (Fed Cir. 2014). NanoBio[®] Protect alone can and should define the scope of any judgment in this litigation. *Id.*

Trutek cites to *Amgen v. F. Hoffman-LaRoche Ltd.* in a futile attempt to drag the developmental vaccines back into this case, while still acknowledging that “it cannot currently proceed with claims based on the developmental vaccines.” ECF 93 at 9. In any event, *Hoffman-LaRoche* is factually distinguishable. While Hoffman-LaRoche had engaged in “meaningful preparation” by completing several clinical trials, building a manufacturing facility, hiring personnel **and filing an FDA**

¹ Trutek mischaracterizes the summary judgment order. ECF 93 at 6. The Court granted the motion for “summary judgment of no damages.” ECF 84 at 52.

application, BlueWillow's developmental vaccines are much earlier in the pre-clinical and clinical testing process, BlueWillow has not yet filed any applications for FDA approval, and the products are years away from entering the market, if ever. *Amgen v. F. Hoffman-LaRoche Ltd.*, 456 F. Supp. 2d 267, 277 (D. Mass. 2006); *see also Telectronics Pacing Sys. v. Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed. Cir. 1992) (device was still years away from potential approval); *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1346-48 (Fed. Cir. 2007) (agreeing that defendant's drug could not infringe until, at least, defendant submits a New Drug Application and finding no controversy between the parties sufficient to support declaratory judgment jurisdiction); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 112 (D. Mass. 1998) (FDA process was uncertain and product may be altered in ways relevant to infringement analysis); *Abbott Diabetes Care, Inc. v. DexCom, Inc.*, No. 05-590 GMS, 2006 WL 2375035, at *2-3 (D. Del. Aug. 16, 2006) (dismissing declaratory judgment claim when FDA had not approved the product, nor could defendant predict when, or if, it would receive approval). Citation to *Already, LLC v. Nike, Inc.* is equally unavailing because the future products in that case, sneakers, are not afforded the same 35 U.S.C. § 271(e)(1) safe harbor protections as BlueWillow's developmental vaccines. 568 U.S. 85 (2013).

More concerning, Trutek's arguments would gut the protections of 35 U.S.C. § 271(e)(1) by overriding that safe harbor for any developmental product with

alleged but unproven similarities to a litigated product. In addition, Trutek offers no factual basis for its allegation that “the cationic surfactant adjuvant technology used to deliver [the developmental vaccines] is nonetheless relevant to the present litigation as it is the same cationic technology at issue with the nasal product.” ECF 93 at 9. There has been no discovery, fact or expert, into the composition of the vaccine adjuvant. Trutek’s speculative allegation is demonstrably false as well. Declaration of Chad Costley (Ex. 1, “Costley Decl.”), ¶ 7 (nanoemulsion adjuvant in the vaccine candidates is different from the NanoBio[®] Protect formulation in terms of both ingredients and concentration). Such arguments should not be permitted and to the extent Trutek requests relief that is targeted to products other than NanoBio[®] Protect, or justifies proceeding with its claims against NanoBio[®] Protect because of purported “similarities” to the vaccines, it should be denied.²

B. Trutek’s Request for Injunctive Relief Is Moot

BlueWillow has shown the “allegedly wrong behavior,” here, sale of NanoBio[®] Protect, “cannot reasonably be expected to recur” and therefore moots the

² Trutek’s arguments based on the vaccine candidates are fatally flawed for another reason. Vaccines operate according to a different mechanism of action. Costley Decl., ¶ 3 (vaccines trigger an immune response to fight a later infection; they “do not kill, inactivate, or disable pathogens” at the time they are administered). As such, the vaccines do not satisfy at least one limitation of each asserted independent claim. More specifically, the vaccines do not “inactivat[] the particulate matter” or “render said particulate matter harmless.” ’802 patent claims 1 and 2.

remainder of Trutek's claims for relief that were actually pled. *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000). Trutek provides no evidence that BlueWillow intends to resume selling NanoBio[®] Protect because there is none. Costley Decl., ¶ 8. Instead, Trutek relies on the same baseless and unlitigated assertion that NanoBio[®] Protect and the vaccines share the same underlying (and supposedly infringing) technology. ECF 93 at 10. Once again, this argument is factually inaccurate and should be ignored. Costley Decl., ¶ 7.

Unlike the shoes and trademarks at issue in *Already*, pharmaceutical products such as vaccines require years of development and agency approval before coming to market. 568 U.S. at 88; Costley Decl., ¶ 4. It strains credulity that BlueWillow's developmental vaccines, which are only in pre-clinical and/or Phase I clinical testing, pose an "imminent" threat of infringement when they are at least five years away from approval. ECF 93 at 8; Costley Decl., ¶¶ 5-6. Indeed, as Trutek states, once these vaccines are on the market, they will no longer be covered by the safe harbor. *Id.* Trutek is welcome to file a case when, or if, that ever occurs,³ and infringement can be properly evaluated through discovery and expert evaluation. Until then, any future injury is speculative, and Trutek's claims are moot.

³ Moreover, BlueWillow's vaccines may not even be approved before the '802 patent expires in May 2029. *See* Costley Decl., ¶ 6.

C. Trutek Lacks Standing to Maintain the Case, Which Must Be Dismissed

Trutek argues two forms of injury: (1) past injury from NanoBio[®] Protect sales and (2) speculative potential future injury from the developmental vaccines. ECF 93 at 14. Only one injury was pled (ECF 1 at 7), but neither is sufficient to support standing. Trutek does not dispute that injury due to NanoBio[®] Protect is based solely on past action, as there are no ongoing sales. Trutek is not entitled to damages, ECF 84, and injunctive relief would not remedy this injury because any injunction would be wholly cumulative of what BlueWillow has already done voluntarily: halt sales of NanoBio[®] Protect. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 107 (1998) (“Relief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court; that is the very essence of the redressability requirement.”).

To the extent Trutek may face future injury from sale of the vaccines, if they complete testing and are approved, it is more appropriate to address that speculative injury when, and if, it occurs. At the very least, any alleged infringement of the approved vaccine products needs to be evaluated. No discovery on the vaccines has occurred (nor would it have been permitted) and Trutek has only offered unsupported and factually inaccurate attorney argument that the vaccines would infringe. These allegations are insufficient to support standing. Because the only injury Trutek has suffered is not redressable, its claim is moot and must be dismissed.

D. The Court Should Decline to Consider Trutek’s Untimely and Speculative Request for Declaratory Relief

Trutek makes no attempt to demonstrate it has pled a claim for declaratory relief. It never sought to amend the complaint and instead seems to believe that its Motion for Summary Judgment is equivalent to a claim for declaratory judgment. ECF 93 at 15 (citing ECF 62). Further, Trutek has not identified any cases demonstrating why the Court can issue a declaration of patent validity (there are no such cases).⁴ ECF 92 at 15 n.3.

Trutek’s claim of infringement by NanoBio[®] Protect is moot, and thus, the Court has no power to issue declaratory judgment. *See Sierra Club v. U.S. Fish & Wildlife Serv.*, 189 F. Supp. 2d 684, 693 (W.D. Mich. 2002) (“[F]ederal courts cannot issue declaratory or injunctive relief as to moot cases.”). Instead, Trutek continues to rely on the non-litigated and safe harbor-protected vaccines to support alleged entitlement to declaratory judgment. ECF 93 at 11-13. The Court has already ruled the “vaccines plainly fall into the safe harbor provision.” ECF 32 at 3. Nothing more needs to be said, and the remainder of Trutek’s arguments must be ignored.

⁴ Trutek’s citations on this point are misplaced. In *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 100-101 (1993) and *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 330 (1945), the Court notes the public interest in finding a patent invalid but does not speak to a patentee’s interest in a patent being declared not invalid. *GE Co. v. Nintendo Co., Ltd.* concerned appellate review of a lower court decision, not the duties of that lower court. 179 F.3d 1350, 1356 (Fed. Cir. 1999).

Trutek's renewed citation to *Amgen v. Hoffman-LaRoche* is unhelpful here as well. Notably, Amgen sought declaratory judgment for products actually named in the complaint, unlike here. 456 F. Supp. 2d at 270. Trutek's brief represents nothing more than pages of unsupported attorney argument for why the vaccines infringe even though the issue was never litigated in this case. ECF 93 at 16-17. It claims unproven facts "suggest" the developmental vaccines would infringe, far from the assurance a court would seek before issuing declaratory judgment as to the products.

E. There Are No Additional Unresolved Matters Which Would Justify This Case Continuing

The "additional matters" Trutek raises are just as speculative and meritless as its other arguments. Trutek's Motion for Reconsideration (ECF 89) belatedly raises arguments it has waived, is contrary to Trutek's discovery in the case, and, even if granted, would not change the status of the case or the outcome of the summary judgment order.⁵ In short, Trutek has not satisfied the requirements of Local Rule 7.1(h)(2)(A), which only permits motions for reconsideration where the "Court made a mistake, correcting the mistake changes the outcome of the prior decision, and the mistake was based on the record and law before the court at the time of its prior

⁵ BlueWillow briefly responds to arguments raised in Trutek's Motion for Reconsideration (ECF 89) as addressed in Trutek's brief on mootness (ECF 93). Due to briefing limits, BlueWillow respectfully requests the opportunity to file a separate opposition should the Court be inclined to consider Trutek's Motion.

decision.” Arguments raised for the first time in motions for reconsideration are waived. *Am. Meat Inst. v. Pridgeon*, 724 F.2d 45, 47 (6th Cir. 1984).⁶

Trutek’s Motion for Reconsideration is premised on the court’s reliance on a supposed factual error in reaching its decision on BlueWillow’s Motion for Summary Judgment with respect to pre-suit damages. ECF 89 at 6. However, the only mistake made was Trutek’s own. The fact relied on was presented in BlueWillow’s Motion for Summary Judgment, ECF 59, 59-3 (Peterson Decl., Ex. 9), and was consistent with materials Trutek produced during discovery (ECF 88 at 6 (TT000112) (filed under seal)). Trutek should have raised any such error in its opposition to summary judgment but it failed to do so and has now waived the argument. *Smith ex rel. Smith v. Mount Pleasant Public Schools*, 298 F. Supp. 2d 636, 637 (E.D. Mich. 2003) (motions for reconsideration are not permitted to “advance positions that could have been argued earlier but were not”). Indeed, the alleged factual error comes directly from Trutek’s own information, and Trutek provides no explanation for why it previously omitted it. ECF 88, ¶¶ 10-11. Either Trutek has misled the court in its Motion for Reconsideration, or its sworn declaration (ECF 89-1) was untruthful.

⁶ Trutek’s new and previously undisclosed argument about “sales commissions and fees” as a basis for a reasonably royalty based on *Spectralytics* is likewise waived.

Finally, granting Trutek's Motion would not change the outcome of the summary judgment decision or the litigation, despite Trutek's arguments. First, the Court's decision was based on the allegedly incorrect fact and numerous other facts. ECF 84 at 56-58. Trutek does not challenge the other evidence. Thus, even if the Court reconsiders this one fact (it should not), there is other evidence to support its decision on pre-suit damages. Second, even if the Court reconsiders whether Trutek complied with the marking statute, Trutek is still barred from introducing any previously "undisclosed damages evidence, including unidentified testimony from unidentified damages witnesses, in support of undisclosed damages theories." ECF 84 at 35. As explained by the Court, Trutek did not disclose any damages theory (pre-suit or post-suit) relying on the sales information. As such, Trutek is barred from pursuing any damages theory, pre-suit or post-suit, by the remainder of the summary judgment decision that Trutek does not challenge. In other words, even if Trutek complied with the marking statute, Trutek is still barred from proving the amount of pre-suit damages and there can be no recovery. Once again, Trutek's arguments are too late, lack merit, and do not justify permitting this case to continue.

III. CONCLUSION

For the reasons stated herein, Trutek's complaint should be dismissed with prejudice and Trutek should not be given leave to refile.

Dated: January 12, 2024

Respectfully submitted,

Foley & Lardner LLP

/s/ Nicholas J. Ellis

Nicholas J. Ellis (P73174)
500 Woodward Ave., Suite 2700
Detroit, MI 48226-3489
Telephone: 313.234.7100
Facsimile: 313.234.2800

Liane M. Peterson
3000 K Street NW, Suite 600
Washington, DC 20007
Telephone: 202.672.5300
Facsimile: 202.672.5399

*Attorneys for Defendant
BlueWillow Biologics, Inc.*

CERTIFICATE OF SERVICE

I hereby certify that, on January 12, 2024, I filed the foregoing document and this Certificate of Service with the Court using the ECF system.

/s/ Nicholas J. Ellis